this population. Results also suggest that the knowledge gap is greater among males than females. This in mind, PPPP includes culturally sensitive elements such as a skit developed by community members and small group discussions to engage the population in conversations about pneumonia.

PIN83

DEVELOPMENT OF A PATIENT-REPORTED OUTCOME INSTRUMENT (SKINFECT-PRO) TO STANDARDIZE AND QUALIFY SYMPTOMS OF ACUTE BACTERIAL SKIN AND SKIN STRUCTURE INFECTION (ABSSSI) FNIH BIOMARKERS CONSORTIUM CABP ABSSSI PROJECT TEAM '3

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**OBJECTIVES:** The purpose of this study was to develop a patient-reported outcome (PRO) instrument to assess Acute Bacterial Skin and Skin Structure Infection (ABSSSI) symptoms in patients in clinical trials of antibacterial drugs, consistent with FDA PRO Guidance. **METHODS:** A comprehensive review of the literature and interviews with nine US and European clinical experts informed the development of a concept elicitation (CE) interview guide, and a hypothetical conceptual framework and disease model exploring patients' experience with symptoms of ABSSSI. CE was based on telephone interviews with 34 patients, after which saturation of emergent concepts was reached. Items and response options were generated based on the qualitative data and a draft instrument was prepared with input and review from an international project team of academic and industry antibacterial experts. Subsequently, cognitive debriefing interviews were conducted with 15 ABSSSI patients and 3 clinical experts to assess item readability, relevance, comprehensiveness, and content validity. Items were edited based on feedback from the patients. **RESULTS:** CE subtypes were evaluated and consisted of 13 (38.2%) patients with major abscess, 12 (35.3%) with wound infection, and 9 (26.5%) with cellulitis. In terms of severity, the majority (79.4%) of infections were rated as moderate by clinicians. The mean age of patients was 38.8 years; 64.7% male. Symptoms were common across all ABSSSI subtypes and supported the saturation of concepts. Items were generated for the PRO Instrument using patient terminology. Subsequent cognitive debriefing with patients demonstrated that the items were understandable, relevant, and interpreted as intended. **CONCLUSIONS:** SKINFECT is a PRO instrument developed to evaluate ABSSSI patient symptoms and functioning in clinical studies with documented evidence of content validity. Qualitative data from patients and input from experts formed the basis of the SKINFECT's structure and item pool, and it is now ready for psychometric reliability and validity testing.

PIN84

COMMUNITY-ACQUIRED BACTERIAL PNEUMONIA (CABP): DEVELOPMENT OF A NEW PATIENT-REPORTED OUTCOME (PRO) FNIH BIOMARKERS CONSORTIUM CABP ABSSSI PROJECT TEAM '3

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**OBJECTIVES:** There is a paucity of evidence regarding a well-defined, reliable, and feasible method for measuring efficacy outcomes from a patient perspective in Community-Acquired Bacterial Pneumonia (CABP) trials. Most CABP studies evaluate treatment efficacy on the basis of clinical outcomes; however, there is no patient-reported outcome (PRO) to capture additional symptoms of how patients feel, function, or survive. The goal of this study was to explore CABP symptoms as reported by patients, and to develop a draft PRO instrument designed to comprehensively assess these symptoms. **METHODS:** Concept elicitation was conducted by telephone interviews with patients within 10 days of CABP diagnosis. Data was analyzed using an iterative process to identify themes and concepts and was recorded in a saturation grid. Saturation was monitored according to the FDA PRO guidance. Using this qualitative data, a draft PRO instrument was prepared. Cognitive debriefing interviews were conducted to assess item readability, relevance, comprehensiveness, and content validity. **RESULTS:** Twenty patients participated in concept elicitation interviews. Mean age of the patients was 59.5 years (SD = 18.8, range: 29-90); 45% were female. The most common symptoms reported included a lack of energy or tiredness (n=18), cough (n=16), and shortness of breath (n=16). Nearly half the patients also reported fever, chest pain and general aches/pain as well as significant impacts on their social (n=10) and physical functioning (n=17) related to the skin infection. Subsequent cognitive debriefing in 9 patients and 3 clinical experts demonstrated that the items were understandable, relevant, and interpreted as intended. **CONCLUSIONS:** Qualitative data from patients and input from experts formed the basis of the CABP PRO structure and item pool. These patient-reported CABP symptoms were shown to demonstrate content saturation and concept validity and provide unique information important for both comprehensive evaluation of individuals with CABP and evaluation of new antibacterial treatments.

PIN85

PREFERENCE VALUES FOR HEPATITIS C-RELATED HEALTH STATES FROM MEMBERS OF THE GENERAL PUBLIC IN AUSTRALIA, BRAZIL, FRANCE, ITALY, AND SPAIN

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**OBJECTIVES:** Limited country-specific data exist on health-related quality-of-life (HRQoL) impacts of hepatitis C virus (HCV) infection. The aim of this study was to elicit preference values for HCV-specific health states from general public participants in Australia, Brazil, France, Italy, and Spain. **METHODS:** HCV health state descriptions were based on literature review and clinical expert feedback for the following: asymptomatic and symptomatic mild/moderate HCV, compensated cirrhosis, five decompensated cirrhosis states (hepatocellular carcinoma, ascites, acute and chronic variceal hemorrhage, and hepatic encephalopathy), and liver transplant (first year and subsequent years). These descriptions included key HRQoL impacts (activities, mood, stigma, cognition, and sleep) associated with each state, and were validated by members of the general public. Trained interviewers elicited time trade-off preference values (or, utilities) from a general public sample, quantifying preferences for each health state on a scale of 0 (dead) to 1 (full health). Mean (95% confidence interval) preferences were estimated for each country and adjusted for age and sex using beta and generalized linear models. **RESULTS:** Logical responses from 488 participants were included; approximately 50% were male. Mean ages ranged from 39.1 (Brazil) to 47.7 (Italy) years. Mean values for asymptomatic mild/moderate HCV health states ranged from 0.90 (0.88-0.91; Australia) to 0.79 (0.76-0.81; Brazil); for the acute variceal hemorrhage health state, mean values were 0.27 (0.24-0.29; France) to 0.39 (0.39-0.42; Italy). Mean preferences for compensated cirrhosis ranged from 0.69 (0.33-0.72; Brazil) to 0.77 (0.75-0.79; Australia). Values were less than 0.70 for all decompensated cirrhosis states. Age- and sex-adjusted beta and generalized linear models showed similar results. **CONCLUSIONS:** This study provides estimates of the quality of life decrement associated with severe liver disease health states, from the general public perspective. This information is important for understanding the benefit of early treatment to delay disease progression in patients with HCV.

PIN86

SIGNS, SYMPTOMS, AND EXISTING PATIENT-REPORTED OUTCOME (PRO) MEASURES IN HOSPITAL-ACQUIRED BACTERIAL PNEUMONIA (HABP): A COMPREHENSIVE LITERATURE REVIEW

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**OBJECTIVES:** Standardized methods to measure symptoms and related patient-reported outcomes (PRO) in Hospital-Acquired Bacterial Pneumonia (HABP) are limited. The purpose of this literature review was to identify signs, symptoms, and measurement tools associated with patients' experience of HABP. The results will be used to inform the development of a valid PRO tool for HABP that is consistent with the FDA PRO Guidance. **METHODS:** To identify relevant literature, MEDLINE (1946 to 2014) and EMBASE (1988 to 2014) databases were searched individually and in combination using terms related to Hospital-Acquired Pneumonia (HAP), HABP, signs and symptoms, and patient-reported outcomes. **RESULTS:** The search identified 1384 abstracts. 225 were excluded as duplicates or for missing content. 1145 abstracts were excluded based on pre-specified criteria. The remaining articles were scrutinized for eligibility, resulting in six that met the inclusion criteria. The most frequently cited signs and symptoms of HABP were fever, cough, purulent sputum, dyspnea, rales, chest pain, and elevated respiratory rate. No PRO measures for assessing HABP signs and symptoms were identified in the literature. Current HABP clinical trials have not included end points that directly measure how a patient feels and functions. **CONCLUSIONS:** The HABP literature has historically focused on clinical outcomes to evaluate treatment efficacy and there is currently limited evidence assessing the impact of antibiotic therapies on symptomatology in HABP patients. Endpoints, such as clinical response, clinical cure, and time to event, are only indirect measures of treatment benefit and have not been validated. It is essential to develop reliable, well-defined and clinically relevant endpoints that measure tangible benefits for patients in clinical trials of antibacterial drugs in accordance with the FDA Guidance for PRO measures and HABP. This literature review is the first step in identifying concepts that will be explored further in qualitative interviews with HABP patients.

PIN87

ASSESSING THE IMPACT OF PEGYLATED-INTERFERON/RIBAVIRIN THERAPY DURATION VERSUS VIRAL RESPONSE ON HEALTH-RELATED QUALITY OF LIFE (QOL) OUTCOMES IN CHRONIC HEPATITIS C VIRUS (HCV) PATIENTS, USING MULTIVARIATE MIXED-EFFECTS MODELING

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**OBJECTIVES:** Pegylated-interferon/ribavirin (PR) is commonly used to treat HCV genotype 1 (G1) -infected patients, both as dual therapy or triple therapy, combined with a direct-acting antiviral (DAA). PR-based treatments are associated with high levels of toxicity and decreased QoL. Adding simeprevir as DAA to PR reduces duration of PR-therapy and increases significantly the proportion of patients reaching viral response (VR). The objective of this analysis was to explore the impact of duration of PR therapy and of having VR on the level of impairment of QOL and other patient-reported outcomes (PRO). **METHODS:** Longitudinal QoL/PRO outcomes were analyzed from three randomized clinical trials comparing PR+simeprevir with PR in treatment-naïve HCV-G1 patients: PILLAR (n=316); QUEST-1 (n=394) ; QUEST-2 (n=391). Early responders in the simeprevir arm were allowed to stop PR-therapy at 24 weeks, instead of 48 week PR-therapy. A mixed-effects model was fitted, including age, gender, baseline fibrosis status, time, treatment interaction between time and treatment as covariates, and PR-therapy and viral response as binary time-varying covariates (viral load </≥25 IU/ml). A model was fitted by trial for the EQ-5D valuation index (VI) and visual analog scale (VAS), the Fatigue Symptom Severity scale (FSS) and the Center for Epidemiologic Studies Depression Scale (CES-D). **RESULTS:** Shortened PR-therapy positively impacted all PRO-endpoints consistently across all studies (p-values ranging between <0.0001 and 0.025). The estimated mean for the positive impact on EQ5D-VI were 0.08 (p=0.0001), 0.05 (p=0.025) and 0.08 (p=0.0005)